EXHIBIT A

Should the Court read the portion of O.R.C. § 4729.55(D) and O.A.C. §2729-9-16(H)(1)(e) regarding the security requirements for distributors (Dkt. 3458 at 6), it should also read the following:

O.A.C. 4729-9-05 (2011) (Security Requirements).

(A) All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.

(B) Substantial compliance with the standards set forth in rule 4729-9-11 of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the applicant, licensee or registrant. In evaluating the overall security system of a licensee, registrant or applicant, the state board of pharmacy may consider any of the following factors, as deemed relevant, for compliance with security requirements:

(1) The type of activity conducted;

(2) Type and form of dangerous drugs handled;

(3) Quantity of dangerous drugs handled;

(4) Location of the premises and the relationship such location bears on security needs;

(5) Type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) Type of vaults, safes, and secure enclosures or other storage system (e.g. automatic storage and retrieval system) used;

(7) Type of closures on vaults, safes, and secure enclosures;

(8) Adequacy of key control systems and/or combination lock control systems;

(9) Adequacy of electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

(10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) Adequacy of supervision over authorized employees having access to areas containing dangerous drugs;

(12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) Availability of local police protection or of the licensee's, registrant's or applicant's security personnel, and;

(14) Adequacy of the licensee's, registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.

O.A.C. § 4729-9-16 (2011) (Minimum Requirements for Wholesalers).

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio:

. . .

(C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years . . .;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lighted.

(3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

. . .

(F) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

. . .

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(1) These records shall include, but shall not be limited to, the following information:

(a) The source of the drugs, including the name and principle [sic] address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received, distributed, disposed or returned.

(c) The dates of receipt and distribution of the drugs.

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code.

(e) A system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.

(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(ii) Reports generated by the system shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents and federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents and federal, state, or local law enforcement agency officials.

(b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy, must first send notification to the board.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. A wholesale distributor of dangerous drugs shall have a responsible person pursuant to rule 4729-5-11 of the Administrative Code.

(K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy designated agents and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

(M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(N) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the wholesale distributor being used or implemented.

O.R.C. §4729.55 (Qualifications of a Terminal Distributor)

No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs unless the applicant has furnished satisfactory proof to the state board of pharmacy that:

> (A) The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board.
>
> (B) A pharmacist . . . will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant.
>
> (C) Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs.
>
> (D) Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.

O.R.C. § 4729.75 (2011) (Drug Database)

The State Board of Pharmacy may establish and maintain a drug database to monitor the misuse and diversion of controlled substances . . . and other dangerous drugs . . .

O.R.C. § 4729.77(A) (2011) (Terminal Distributor Pharmacies to Submit Prescription Information)

If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in this state and is included in the types of pharmacies specified in rules adopted under section 4729.84 of the Revised Code shall submit to the board the following prescription information:

> (1) Terminal distributor identification;
>
> (2) Patient identification;
>
> (3) Prescriber identification;
>
> (4) Date prescription was issued by prescriber;
>
> (5) Date drug was dispensed;
>
> (6) Indication of whether the drug dispensed is new or a refill;
>
> (7) Name, strength, and national drug code of the drug dispensed;

(8) Quantity of drug dispensed;

(9) Number of days' supply of drug dispensed;

(10) Serial or prescription number assigned by the terminal distributor;

(11) Source of payment for the drug dispensed.

O.R.C. § 4729.78(A) (2011) (Wholesale Distributors to Submit Purchase Information)

If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each wholesale distributor of dangerous drugs that delivers drugs to prescribers in this state shall submit to the board the following purchase information:

(1) Purchaser identification;

(2) Identification of the drug sold;

(3) Quantity of the drug sold;

(4) Date of sale;

(5) The wholesale distributor's license number issued by the board.

O.R.C. § 4729.79 (2011) (Submission of Information for Database by Licensed Health Processional Who Personally Furnish Controlled Substances, Naltrexone, or Other Dangerous Drugs)

(A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each licensed health professional authorized to prescribe drugs, other than a veterinarian, who personally furnishes a controlled substance or other dangerous drug the board includes in the database . . . to a patient in this state shall submit to the board the following information:

(1) Prescriber identification;

(2) Patient identification;

(3) Date drug was furnished by the prescriber;

(4) Indication of whether the drug furnished is new or a refill;

(5) Name, strength, and national drug code of drug furnished;

(6) Quantity of drug furnished;

(7) Number of days' supply of drug furnished;

(8) Source of payment for the drug furnished.

. . .

(C) If the board becomes aware of a prescriber's failure to comply with this section, the board shall notify the government entity responsible for licensing the prescriber.

O.R.C. § 4729.81 (2013) (Review of Database Information; Investigation)

If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall review the information in the drug database. If the board determines from the review that a violation of law may have occurred, it shall notify the appropriate law enforcement agency or a government entity responsible for the licensure, regulation, or discipline of licensed health professionals authorized to prescribe drugs and supply information required by the agency or entity for an investigation of the violation of law that may have occurred. The board also shall notify the medicaid director if the board determines that the violation may have been committed by a provider of services under a program administered by the department of medicaid.

O.R.C. § 4729.85(B) (2015) (Pharmacy Board to File Biennial Reports; Contents)

If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall prepare reports regarding the database and present or submit them in accordance with both of the following:

. . .

(B) The board shall submit a semiannual report to the governor, the president of the senate, the speaker of the house of representatives, the attorney general, the chairpersons of the standing committees of the house of representatives and the senate that are primarily responsible for considering health and human services issues, the department of public safety, the state dental board, the board of nursing, the state board of optometry, the state medical board, and the state veterinary medical licensing board. The state board of pharmacy shall make the report available to the public on its internet web site. Each report submitted shall include all of the following for the period covered by the report:

(1) An aggregate of the information submitted to the board under section 4729.77 of the Revised Code regarding prescriptions for controlled substances containing opioids, including all of the following:

(a) The number of prescribers who issued the prescriptions;

(b) The number of patients to whom the controlled substances were dispensed;

(c) The average quantity of the controlled substances dispensed per prescription;

(d) The average daily morphine equivalent dose of the controlled substances dispensed per prescription

.

(2) An aggregate of the information submitted to the board under section 4729.79 of the Revised Code regarding controlled substances containing opioids that have been personally furnished to a patient by a prescriber, other than a prescriber who is a veterinarian, including all of the following:

(a) The number of prescribers who personally furnished the controlled substances;

(b) The number of patients to whom the controlled substances were personally furnished;

(c) The average quantity of the controlled substances that were furnished at one time;

(d) The average daily morphine equivalent dose of the controlled substances that were furnished at one time.

Should the Court read the requested portions of O.A.C. §4729-5-21(A) regarding the validity of a prescription (Dkt. 3458 at 6), it should also read the following:

OAC 4729-5-21 (Manner of Processing a Prescription):

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist when dispensing a prescription must:

(1) Ensure that patient information is profiled . . .;

(2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;

(3) Ensure that the drug is labeled . . .;

(4) Ensure that a patient is given an offer to counsel . . .;

(5) Ensure that a prescription is filed . . .